

**Remarks**

The Examiner issued a requirement for restriction of the pending claims according to the following scheme:

Group I        Claims 1-13, drawn to a process for preparing a dosage form, classified in class 514, subclass 54; class 536, subclass 123.12, 123.1, 124; class 424, subclass 439.

Group II       Claims 14-29, drawn to a dosage form, classified in class 514, subclass 54, 849, 853, 867, 886; class 536, subclass 123.12, 123.1, 124; class 424, subclass 439.

The Examiner's comments have been carefully considered and the requirement for restriction is respectfully traversed.

The criteria for restriction is set forth in section 803 of the MPEP as follows:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent or distinct; and
- (B) There must be a serious burden on the examiner if restriction is required. (emphasis added) (internal citations omitted).

Concerning the first prong of §803, the Examiner alleges that the variously defined inventions are independent or distinct because the process as claimed can be used to make other and materially different products, e.g. to make dosage forms or compositions of other polysaccharides. However, it is respectfully pointed out to the Examiner that the dosage forms of claims 14-29 are defined in terms of the processes of Claims 1-13. Therefore, it is submitted that the Examiner has not shown that the process *as claimed* can be used to make other and materially different products.

Concerning the second prong, §803 instructs that examiners establish a "serious burden" by demonstrating one of three *prima facie* elements:

- (A) the inventions have a separate classification;
- (B) the inventions have a separate status in the art; or,
- (C) the inventions have a different field of search, as defined in MPEP § 808.02.

It is respectfully submitted that the Examiner has not satisfied the *prima facie* case with respect to inventions identified as having the same classifications, but different subclassifications. Moreover, the Examiner has not established that examination of inventions sharing the same classification imposes a serious burden. Applicants respectfully submit there is none. The Examiner alleges that the variously defined inventions are "independent" or "distinct" in satisfaction of only the first prong of this two-prong test. However, as § 803 makes clear, independent or distinct inventions must still be examined collectively, i.e., not restricted, unless such examination would impose a serious burden on the examiner. *If the search and examination of the entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (MPEP § 803) (emphasis added).*

Further, Applicants note that corresponding in WO 2004/012720, the International Search Authority did not find unity of the invention to be lacking. Applicants respectfully submit that such determination should be binding on the Examiner herein.

Consistent with the foregoing remarks and in accordance with 37 CFR 1.143, Applicant provisionally elects, with traverse, to prosecute the invention as follows:

Group I          Claims 1-13, drawn to a process for preparing a dosage form

Reconsideration and withdrawal of the requirement for restriction are respectfully requested.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§ 1.16 and 1.17, or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

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